Percutaneous gas-line

Field of the Invention

The present invention relates generally to a heart assist device, system and method and more particularly to a percutaneous gas-line for an implanted medical device such as a left ventricular assist device (LVAD), or counter-pulsation or co-pulsation heart assist device and to a heart assist device incorporating such a gas-line.

Background of the Invention

International PCT patent application no. PCT/US00/22992 (WO 01/13974) discloses a gas-driven device heart assist device, that requires a percutaneous positioned gas-line.

US patent no. 6,132,363 discloses a percutaneous access device (PAD) system, that allows both gas and electrical transmission, that utilises an intermediary connector piece that has the patient's own fibroblasts cultured onto the hub of the PAD. This has the proposed advantage of reducing infection. However, its disadvantages include its large size, inflexible nature, and that implantation is a two or three staged procedure. Specifically, implantation involves making a large skin biopsy, isolating the fibroblasts from the biopsy and growing the cells, then culturing them onto the device (which is a 10 day process). When the culturing process has been completed, the PAD can be implanted in the abdomen, and then the counterpulsation device implanted.

It is an object of the present invention to provide an improved percutaneous gas-line that, at least in preferred embodiments, requires no antecedent preparation and has a low risk profile for infection, but which allows remedial action to be taken in the event that gas-line infection occurs. It is well known that infection related to percutaneous lines in general is influenced by the diameter, flexibility and nature of the material. As such, a smaller, more flexible and soft (particularly Silicone) material are most advantageous in reducing infection – this is in direct contrast to the PAD as disclosed above.

It is a further object to provide a gas line for a heart assist device which gas line incorporates an ECG lead to provide for monitoring of the heart internally of the patient's body to control the operation of the heart assist device.

Summary of the Invention

Accordingly, in a first aspect, the present invention provides a percutaneous gas-line for a medical device, the gas-line including:

a first gas-line part adapted to be wholly implanted in a patient and having a first end adapted for sealing connection to the medical device and a second end with a connection fitting; and

a second gas-line part adapted to be part–implanted and part-external and having a first (external) end adapted for sealing connection to an external driver and a second (implanted) end adapted for removable sealing connection with the connection fitting on the second end of the first gas-line part.

The second gas-line part is preferably further adapted to be removable, for replacement, in the presence of persistent exit-site infection or damage to the external part.

The medical device is preferably a heart assist device, more preferably a left ventricular assist device (LVAD), or a counter-pulsation or co-pulsation heart assist device.

The first (external) end of the second gas line is preferably removably connected to the external driver.

In preferred embodiments of the invention, an ECG lead adapted to connect a patient's heart with a control system for a heart assist device utilising the gas line according to this invention is incorporated into the first gas line part and/or the second gas line part.

The second gas-line part is preferably constructed to have a minimal outside diameter, more preferably less than 7 mm, and has high flexibility and a resistance to kinking or collapsing. The second gas-line part is preferably made of a soft biocompatible, biostable material, such as silicone 45-65A durometer. This gas-line part may be wire-wound internally to allow thin wall and kink/collapse resistance.

The connection fitting is preferably a Luer-lock or similar gas-tight fitting.

The first and/or second gas-line parts preferably have a fluffy polyester, or similar, collar over about a short section (eg. 20-50mm) of their implanted length. The collar being adapted to encourage sub-cuateous tissue ingrowth to help reduce any movement of the gas-line in situ – the collar is preferably at least 20mm from the percutaneous exit site.

In a second aspect, the present invention provides a method of providing heart assistance to a patient using a percutaneous gas-line having a first gas-line part, adapted to be wholly implanted, and a second gas-line part, adapted to be part implanted and part external, connected to the first gas-line part, the method including the steps of:

(1) recognising a persistent exit-site infection;

(2) disconnecting the second gas-line part from the first gas-line part;

(3) removing the second gas-line part from the patient; and

(4) connecting a sterile second gas-line part to the first gas-line part

wherein the fresh second gas-line part is inserted through a fresh exit-site that is remote to the infected exit-site.

It will also be understood by persons skilled in the art that the fresh second gas-line part is inserted through an implant tunnel that is also substantially remote from the existing implant tunnel.

Alternatively, after step (3), the first gas-line part (and the implanted ECG cable, if it is attached to a corresponding interconnect cable associated with the second gas-line part) is sealed and wounds are closed to allow healing to occur (which may include prolonged treatment with antibiotics), at this time the device is non-functional, but can, at a later time, be made functional by re-implanting the second part and sealing attaching it to the first part.

In a third aspect, the present invention provides a gas line for connecting an inflatable heart assist actuator to a driver therefore, the gas line having a first end operatively connected to the inflatable actuator and a second end connectable, directly or indirectly through an extension gas line, to the driver for the heart assist actuator, the gas line having attached to it an ECG lead, the ECG lead having a first end adapted for connection to the heart of a patient and a second end adapted for connection to the driver or a controller for the driver, the attachment between the gas lead and the ECG lead being such that they are adapted to pass through the skin of a patient as a single element.

Brief Description of the Drawings

A preferred embodiment of the invention will now be described, by way of an example only, with reference to the accompanying drawing in which:

Fig. 1 is a schematic view of a percutaneous gas-line according to an embodiment of the invention, connected between an implanted heart assist device and an external driver.

Fig. 2 is a schematic view of a percutaneous gas-line according to a second embodiment of the invention, connected between an implanted heart assist device and an external driver and in which an ECG cable is incorporated into the gas line.

Detailed Description of the Preferred Embodiment

Fig.1 shows a percutaneous gas-line 10 according to a first embodiment of the invention. The gas-line 10 has a first part 10a and a second part 10b.

The gas-line 10 connects an external gas driver 12 to a left ventricle heart assist device 14, which is positioned around a patient's aorta 16. The heart assist device 14 comprises a balloon (not shown), a bushing (not shown), and a wrap 18 to hold the balloon in position around the aorta 16.

The first part 10a of the gas-line 10 has a first end 10a' sealingly connected to the bushing and in gas communication with the balloon. The first part 10a of the gas-line 10 also has a second end 10a" with a gas-tight Leur-lock fitting 20 thereon. The first part 10a of the gas-line 10 is made of a polyurethane-polysiloxane block co-polymer similar to that used to form the balloon and bushing.

The second part 10b of the gas-line 10 is shown positioned percutaneous through an exit site 22. The external/un-implanted portion of the second part 10b has a first end 10b' that is connected to the external driver 12 with a gas tight but removable fitting. The second gas-line part 10b also has a second end 10b" connected to the second end 10a" of the first part 10a at the Luer fitting 20. The implanted portion of the second part 10b also has about it a polyester collar 24 for anchoring the gas-line subcutaneously approx 20-50 mm from an exit site 22.

The second part 10b can be made of a different material to the first part 10a. It is preferably made of silicone or silicone-polyurethane co-polymer. The second part 10b can also be more flexible than the first part 10a and can be wire-wound.

In the event that the external part of the gas-line 10 is damaged in every-day use, or if a persistent infection develops at the exit site 24, then the second part 10b is able to be exchanged for a fresh/new (sterilised) second part 10b which is brought out of the patient via a new exit–site 24 (see phantom lines). As this can be done without need to replace the whole heart assist device arrangement, the surgery is minimal. More particularly, the surgery only involves a small incision (not shown) over the subcutaneous connection, undoing of the connection of the Luer lock 20, and removal of the second part 10b. A new exit-site 24 is then made, and a new second part 10b tunnelled through to the first incision for reconnection of the first 10a and (new) second 10b parts. If the infection has travelled up the original second gas line part 10b then the fresh second gas-line part is inserted through an implant tunnel that is also substantially remote from the existing implant tunnel.

Fig. 2 shows a percutaneous gas-line 10' according to a second embodiment of the invention. Like features to those of the first embodiment are indicated with like reference numerals in the second embodiment.

The gas-line 10' includes a first part (implanted) epicardial ECG lead 26, a sleeve 28 and a second part (percutaneous) ECG lead 30. The lead 26 enters the sleeve 28, which is connected between the first and second parts of the gas line 10a and 10b. The sleeve 28 has an electrical connector therein (not shown) that connects the lead 26 to an extension of the lead 30. The lead parts 26 and 30 therefore advantageously provide direct communication of ECG signals from the patient's heart to the driver 12.

The lead 30 is connected to the driver 12 and is contained within the interior of the gas-line second part 10b. Alternatively, the lead 30 can be glued to the exterior of the gas-line second part 10b. In either case, only a single exit site 22 is required, thereby minimising infection risk and patient discomfort.

It will be appreciated by the persons skilled in the art that numerous variations and/or modifications can be made to the invention as shown in the specific embodiment without departing from the spirit or scope of the invention as broadly defined. For example, the blood displacing devices are described above in relation to extra-aortic counter-pulsation but also suitable for intra aortic counter-pulsation devices, co-pulsation devices, or pneumatic driven LVADs.